U.S. Department of Justice
Drug Enforcement Administration

REPORT OF INVESTIGATION

1. Program Code	2. Cross Related Files File	3. File No. [redacted]	4. G-DEP Identifier [redacted]
5. By: Roshaun M McElhenny, DI At: ORLANDO, FL DISTRICT OFFICE	☐ ☐ ☐ ☐ ☐	6. File Title Publix Super Markets, Inc., Rocket Court Warehouse	
7. ☐ Closed ☐ Requested Action Completed ☐ Action Requested By:		8. Date Prepared 07-19-2019	

9. Other Officers:

10. Report Re: Preparation for On-site Inspection of Publix Super Markets, Inc., Rocket Court Warehouse; 10400 Rocket Ct, Orlando, FL 32824; DEA# RP0500391 [redacted]

DETAILS

1. This case was initiated by the Orlando District Office Diversion Group in accordance with the Fiscal Year 2019 Work Plan for the Miami Field Division. PUBLIX SUPER MARKETS, INC., ROCKET COURT WAREHOUSE, is registered with DEA as a Distributor in schedule 2-5 controlled substances, located at 10400 Rocket Ct, Orlando, FL 32824, under DEA Registration Number RP0500391.

2. On July 19, 2019, Diversion Investigator Roshaun McElhenny accessed and reviewed the DEA Suspicious Order Reporting System (SORS), requested Automated Reports Consolidated Orders System (ARCOS) analysis and the Controlled Substance Ordering System (CSOS) history on PUBLIX SUPER MARKETS, INC., ROCKET COURT WAREHOUSE in anticipation of the on-site inspection.

3. Diversion Investigator McElhenny also reviewed the Drug Theft and Loss database for the past two (2) years which revealed 38 Theft and Loss Reports in 2018 and two (2) Theft and Loss Reports in 2019.

4. This file remains open pending the on-site inspection.

INDEXING

[redacted]

11. Distribution:	12. Signature (Agent)	13. Date
Division District Other [redacted]	/s/ Roshaun M McElhenny, DI	07-19-2019
	14. Approved (Name and Title) /s/ James W Graumlich, GS	15. Date 07-22-2019

DEA Form - 6
(Jul. 1996)

DEA SENSITIVE
Drug Enforcement Administration

U.S. Department of Justice
Drug Enforcement Administration

REPORT OF INVESTIGATION

1. Program Code	2. Cross Related Files File	3. File No. [redacted]	4. G-DEP Identifier [redacted]
5. By: Richard J Albert, DI At:	☐ ☐ ☐ ☐ ☐	6. File Title Publix Super Markets, Inc., Rocket Court Warehouse	
7. ☐ Closed ☐ Requested Action Completed ☐ Action Requested By:		8. Date Prepared 12-02-2020	

9. Other Officers: DI Derek Uban and DI Sturgeon Tate

10. Report Re: In-Depth; PUBLIX SUPER MARKETS, INC., 10400 Rocket Court, Orlando, FL 32824; DEA# RP0500391 [redacted]

SYNOPSIS

This Scheduled In-Depth Investigation was initiated pursuant to Fiscal Year 2019 Investigative Work Plan for the Miami Field Division, Orlando District Office. PUBLIX SUPER MARKETS, INC. is registered with DEA #RP0500391 as a Distributor in schedules 2-5 at 10400 Rocket Court, Orlando, Florida 32824, expiration date March 31, 2020.

The on-site portion of the inspection took place on September 26, 2019, September 30, 2019, and concluded on October 4, 2019. Investigators conducted an accountability audit of controlled substances handled by the firm which disclosed no significant record keeping violations.

Prior to the inspection, information contained in DEA databases including Registrant Information Consolidated System (RICS), Controlled Substance Ordering System (CSOS), Automated Reports Consolidated Orders System (ARCOS) and Drug Theft/Loss (DTL) was gathered to assist Investigators with the inspection.

Based on ARCOS records and a review of the firm's sales, DI McElhenny identified and audited the following 8 drugs:

Oxycodone hydrochloride 5mg

Fentanyl transdermal system 25mcg

Methylphenidate hydrochloride 10 mg ER

Hydrocodone Bitartrate acetaminophen 10 mg/325 mg

11. Distribution: Division District Other [redacted]	12. Signature (Agent) /s/ Richard J Albert, DI	13. Date 12-02-2020
	14. Approved (Name and Title) /s/ James W Graumlich, GS	15. Date 12-14-2020

DEA Form - 6
(Jul. 1996)

DEA SENSITIVE
Drug Enforcement Administration

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Clonazepam 2 mg

Tramadol hydrochloride 100mg ER

Buprenorphine and naloxone 8 mg/2 mg

Alprazolam 2 mg

The audit period ran from Close of Business August 24, 2018 to Close of Business September 26, 2019. The audit revealed no discrepancies.

NOTE: Diversion Investigator (DI) Roshaun McElhenny conducted the on-site investigation and DI Richard Albert inherited the open in-depth and is completing this Report of Investigation (ROI) based on the original draft by DI McElhenny.

This case remains open pending review of the firms Suspicious Order Reporting and Due Diligence Files.

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ENCLOSURES

1. SORS Flow Chart

2. Notice of Inspection

3. Computation Chart

4. Closing Inventory

5. Alarm Verification

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DETAILS

BASIS FOR INVESTIGATION

1. This investigation was initiated pursuant to the Fiscal Year 2019 Regulatory Work Plan for the Miami Field Division, Orlando District Office, Diversion Group. PUBLIX SUPER MARKETS, INC. is registered with DEA #RP0500391 as a Distributor in schedules 2-5 at 10400 Rocket Court, Orlando, Florida 32824.

SUBJECT FIRM'S BACKGROUND

2. PUBLIX was incorporated in the State of Florida in 1921 under document number 112252. The main branch headquarters office is located at 3300 Publix Corporate Parkway, Lakeland, Florida 33811. The following individuals were provided as corporate officers:

-President/CEO Randall T. JONES, DOB: [redacted]

-General Counsel/Vice President and Secretary Merriann M. METZ, DOB: [redacted]

-Executive Vice President/CFO David P. PHILLIPS, DOB: [redacted]

-Vice President of Distribution Mike LESTER, DOB: [redacted]

A check in NADDIS revealed no derogatory information.

3. The distribution center supplies schedule 2-5 controlled substances to approximately 1,042 company-owned pharmacies located in seven states; Florida, Alabama, Georgia, North and South Carolina, Tennessee, and Virginia. The company was previously registered as a distributor of schedule 3-5 controlled substances with DEA number RP0331924 at 1950 Sand Lake Road, Building 3, Orlando, Florida 32809, which was retired on October 20, 2016.

4. PUBLIX holds the following licenses:

-State of Florida, Department of Business and Professional Regulation, Prescription Drug Wholesale Distributor, License #2220241, expiration June 30, 2020

-South Carolina Controlled Substances Act Certificate of Registration 40-16810 in schedules 2-5, expiration April 1, 2020

-South Carolina Department of Labor, Licensing and Regulation, Board of Pharmacy Non-Resident Wholesaler, Distributor/Manufacturer Permit #16810, expiration June 30, 2020

-Alabama State Board of Pharmacy, Wholesaler Precursor License #700223, expiration December 31, 2020

-North Carolina Controlled Substances Registration Certificate #NC-DHHS-1000387, expiration December 31, 2019

-State of Georgia Department of Community Health, Wholesaler Pharmacy Permit #PHWH004035, expiration June 30, 2021

It should be noted that the State of Tennessee and the State of Virginia advised PUBLIX that the firm did not require licensure due to the fact the distribution of prescription drugs from Publix wholesale distribution center in Florida to Publix retail pharmacies is considered an intracompany sale or distribution.

5. A check of DEA's databases revealed the following investigative history for the registrant under its current DEA registration:

[redacted] Approval of Application, Distributor in Schedules 2-5 (DEA# RP0500391)

[redacted] Approval of Application, Distributor in Schedules 3-5 (DEA# RP0331924)

[redacted]; Scheduled In-Depth, No violations (DEA# RP0331924)

[redacted]; Scheduled In-Depth, No violations (DEA# RP0331924)

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[redacted] Scheduled In-depth, No violations (DEA# RP0500391)

The distribution center operates with one hundred and fourteen (114) full time employees. Picking of controlled substances occurs between 4:30am and 1:30pm.

6. Suspicious Orders Reporting: Chris HEWELL, Manager for Procurement, explained the firm's system for identifying and reporting suspicious orders and provided a SORS Flow Chart **(ENCLOSURE 1)**. PUBLIX first obtained its DEA registration at this location in 2016. Since the initial registration date, PUBLIX has interrogated and tracked orders using SOMLink suspicious order monitoring software. In addition to SOMLink, schedule 2 controlled substance orders also are assessed by CSOS administrators. In 2018, PUBLIX centralized the process of reviewing and evaluating flagged orders through its Pharmacy Compliance Department.

Publix Inventory Management Software generates product requests to meet each pharmacy's forecasted demand. In addition, pharmacy associates can manually request product (e.g., new patient arrives after a pre-defined product request is generated). Automated product requests consider pending inbound inventory. Pharmacists may review and modify automated and manual product requests before they are transmitted. Requests for schedule 2 controlled substances are individually reviewed and approved by dedicated CSOS administrators prior to receipt by the warehouse. Once a request is approved, the central reviewer (i.e., CSOS administrator) is the individual who actually issues the order using his/her digital certificate. Product requests are based on the on-hand inventory and minimum shelf stock inventory required for forecasted demand.

Orders are interrogated by the SOMLink suspicious order monitoring system prior to receipt by Distribution. Any order that is flagged by SOMLink (i.e., and order of interest) is reviewed and cleared by a Pharmacy Compliance Analyst. In addition to SOMLink, schedule 2 controlled substance orders are also assessed by CSOS administrators. PUBLIX's SORS are designed to detect orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. Orders of interest are flagged by: (a) CSOS administrators reviewing orders for unusual size; and (b) SOMLink when orders (i) exceed

anticipated demand (i.e., established thresholds) or (ii) are flagged by SOMLink Analytic Tests (i.e., algorithms) designed to address size, pattern, and frequency.

A schedule 2 controlled substance item flagged by a CSOS administrator is omitted from distribution and flagged for additional analysis. An item flagged by SOMLink is automatically omitted from the order (i.e. not shipped) without regard to whether it is, in fact, suspicious. It is then queued for review by the Pharmacy Compliance Department as an order of interest. A Compliance Analyst investigates each order of interest and either confirms whether the order should be reported as suspicious; or obtains credible evidence to conclude the order is not suspicious. Supporting documentation is maintained in the SOMLink system, internal network drives, and in a summary case report.

The flagged order review considers relevant information which, on a case by case basis, may include such things as dispensing history, forecasted demand, minimum/maximum order points, the current balance on hand, prescription level information, inventory adjustments, store's local market/business evaluation, and industry evaluation, among other data points. The Pharmacy Compliance Department will determine if the flagged order is suspicious or not. The requesting pharmacy will need to issue a second request for the product because the initial order of interest was omitted/killed without regard to whether it was suspicious. All orders deemed suspicious are reported to the DEA. The Pharmacy Compliance Department prepares the DEA notification. PUBLIX Corporate Legal submits the notification via fax to the DEA Orlando District Office. Publix's policy is to report all orders deemed suspicious to the DEA, so there are no scenarios where an order is determined to be suspicious and not reported to DEA.

PERSONS INTERVIEWED AND INDIVIDUAL RESPONSIBILITY

7. On September 26, 2019, DI Roshaun McElhenny and DI Derek Uban of the Orlando District Office presented their credentials to Laura SLONE, Pharmacy Department Manager. DI McElhenny issued Ms. SLONE a DEA Form 82, Notice of Inspection. Ms. SLONE read the Notice of Inspection pursuant to

1316.08(b) and signed it, thereby consenting to the inspection **(ENCLOSURE 2).**

SCOPE OF INVESTIGATION

8. The on-site portion of this Scheduled Investigation was initiated on September 26, 2019 and concluded on September 30, 2019. DI McElhenny and DI Uban were assisted by Ms. SLONE and Jasmine RODRIGUEZ, Compliance and Regulatory Specialist, Pharmacy Distribution Center. The controlled substance accountability period extended from August 24, 2018 Close of Business (COB), through September 26, 2019 COB. The following controlled substances were selected for the audit based on the quantities held and potential for abuse:

Oxycodone hydrochloride 5mg

Fentanyl transdermal system 25mcg

Methylphenidate hydrochloride 10 mg ER

Hydrocodone Bitartrate acetaminophen 10 mg/325 mg

Clonazepam 2 mg

Tramadol hydrochloride 100mg ER

Buprenorphine and naloxone 8 mg/2 mg

Alprazolam 2 mg

9. The audit revealed no discrepancies. The results of the controlled substance audit are shown on the computation chart as **Enclosure 3.**

10. A review of selected purchase and distribution records revealed no violations of DEA recordkeeping or reporting requirements. The records were maintained in a manner consistent with the recordkeeping requirements per 21 CFR 1310.

RECORDKEEPING

1. Initial Inventory: The Initial Inventory figures were taken from the firm's Biennial Inventory conducted on August 24, 2018 at Close of Business. Ms. SLONE is responsible for the accuracy of this inventory.

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2. Biennial Inventory: The firm's Biennial Inventory was taken on August 24, 2018 Close of Business, as required by CFR 1304.11c. It was found to have all the required information.

3. Closing Inventory: On September 26, 2019 DI McElhenny and DI Uban took a physical inventory of the controlled substances to be audited with the assistance of Ms. SLONE and Ms. RODRIGUEZ. The closing inventory was determined as September 26, 2019, Close of Business. Ms. SLONE verified and attested to the accuracy of the closing count by signing the DEA Closing Inventory Form **(Enclosure 4).**

4. Receipts: The firm's primary Schedule 2 receiving document is the CSOS record. All CSOS records are maintained in the firm's computer system at its Lakeland, FL headquarters, but are available at the registered location.

The firm's primary receipt record for schedule 3-5 controlled substances consists of a purchase order which includes all the information required by DEA. The purchase order contains the name of the firm, order number, quantity, product description and the date received. The actual date an item is physically received is documented on this record. The invoice is attached to all other paperwork pertaining to the purchase of controlled substances, including the firm's purchase order, the vendor's shipping list, a freight bill prepared by PUBLIX and a freight log. The original purchase records for schedule 3-5 controlled substances are maintained on the premises.

The firm also maintains computer-generated transaction reports in its computer database. The transaction reports show the product name, strength, size, invoice and purchase order, quantity, date the purchase order was closed, transaction date, and store identification. Investigators used these computer printouts to assist in the audit, comparing purchases to the original paperwork to verify receipt dates.

5. Production Records: N/A

6. Distribution Records: The firm's primary distribution record for schedule 2 drugs are maintained in the CSOS system. All CSOS records are maintained in the firm's computer system at its Lakeland, FL headquarters, but are available at the registered location.

The primary record for Schedule 3-5 distributions is the firm's pick slip, a computer generated invoice, and the manifest. Manifests are maintained by date and stored in the Information Services Department. All original

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hard copies go to the store which the controlled substances are shipped to. Ms. SLONE stated the firm verifies each customer's DEA registration prior to filling and processing an order. The firm's computer system will not generate an invoice if the DEA registration has expired. The DEA number and expiration date are printed on each shipping invoice.

All PUBLIX pharmacies use the firm's closed system, proprietary software to order controlled substances from the PUBLIX distribution center. The warehouse accepts or rejects the order from its stores. The firm generates pick slips via an interactive voice system used by warehouse personnel to fill orders. The distribution of each controlled substance is inventoried, cross checked, and inspected prior to shipping. Each distribution is documented and tracked in the firm's computer system by item number. All controlled substances orders are pulled and checked by at least 3 individuals before being placed in totes and transferred to the shipping dock. The individuals are identified as a Selector, Order Checker and Dock Coordinator. All three individuals must verify the count before items are shipped.

The Publix shipping system receives orders electronically into the Warehouse Management System. The order is picked/checked/packaged as follows: First, the order is sent to the selector's headset via Inventory Management Software. The selector then picks and places the products ordered in the tote. The tote is staged for quality control. During the quality control process, order "checkers" reconcile the products in the tote against the order using a handheld scanning tool. Once the schedule 2 controlled substance order passes quality control, the products are placed in a tamper-resistant sealed bag and the tote is closed with the tote ties. Schedule 3-5 controlled substances follow a similar quality control process. Once the schedule 3-5 controlled substance order passes quality control, the tote is closed with the tote ties and all schedule 2-5 controlled substances sealed totes are staged to be merged with shipping pallets. Totes are secured with serialized tote ties under cameras within the designated controls area (e.g. cage or vault). The totes are scanned out of the warehouse (for creation of the advanced shipment notice file) and promptly placed on the receiving courier's trailer for distribution to the destination pharmacy. Totes containing controlled substances do not differ from totes that do not contain controlled substances (e.g. no

specific colors or markings). Totes are delivered to the store by a courier. Totes are received at the store by serialized tote ties and labels being scanned into the Prescription Receiving Application at the store. The manifest is reviewed, discrepancies noted (if any), initialed, and dated. The product within each tote is scanned into the Prescription Receiving Application. Only Pharmacists and/or Pharmacy Technicians can scan in totes and sign manifests. Only the Pharmacist can scan and receive controlled substance products. All tote and product level receiving is documented with user-IDs and time stamps stored in a database.

Order pickers wear a wireless headset that is connected to a voice system. Once the picker receives the order, the computer generates a screen line for the same invoice. The picker logs on and begins picking. Once each item is picked it must be scanned by the picker and placed into a tote. If the item does not match the computer data, an error message is displayed and a voice message is relayed to the operator to choose the correct item. The scan code is based on the NDC number. The computer will not allow an invoice to be printed and closed until the error has been corrected. Orders are packed in a brown bag while in the cage but the box is not sealed until sent down the line to be boxed with non-controlled items. The shipping section closes all totes with a piece of PUBLIX security tape. Once the order is completed outside of the cage, an invoice is generated (computer invoice printed for the box). PUBLIX loads the totes containing controlled substances onto a short conveyor belt outside of the controlled substances' cage where the totes travel to the loading bays via the motorized conveyor belt system, stopping for verification in the distribution area. The conveyor belt is approximately 15 feet long and is within sight of operators. The single individual working in this area will not open any totes, but instead verify the label and order information on the outside of the tote against a printout. The totes are sent to the shipping department where they are sorted by route and funneled to the appropriate truck for delivery. Controlled substances totes do not sit on the loading bay. Every loading bay has cameras looking into the truck as it is loaded. The firm has a full time security staff monitoring the camera views. This information is digitally recorded and maintained for 60 days. When the semi-trailers are not being actively loaded and manned, the security door will be closed and locked. The firm

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utilizes a delivery truck service contracted through McKesson, Monday through Thursday. On Friday, the firm utilizes a third party carrier called Carrier Advertise Group. When goods are delivered, all loaded boxes will have the pharmacy designated on the box. A pharmacy associate must sign for the controlled substances. The driver obtains a signed freight log and delivery log from pharmacy personnel.

7. Records of Returned or Damaged Goods: Damaged or expired goods that are received from the supplier will be returned to the supplier and a credit memo generated, or the products will be destroyed using an authorized destruction facility. The firm does not accept returns from their stores. All stores are internally equipped to handle the disposition of controlled substances in their possession. The return documents and credit memos are filed in the quarantine cage. The firm utilizes a quarantine cage to store substances that are in a holding status pending destruction or return.

8. ARCOS: The firm's Information Services Department is responsible for reporting to DEA's ARCOS system. Prior to the on-site inspection, DI McElhenny obtained an ARCOS transaction report from the ARCOS Targeting and Analysis section. According to the Targeting and Analysis Unit, the firm reported the following: 3,930 total dosages of methylphenidate, 606 total dosages of buprenorphine, 17,600 total dosages of oxycodone, 21,360 total dosages of hydrocodone, and 2,460 total dosages of fentanyl base. INMAR RX SOLUTIONS, INC is a reverse distributor and reported the following: 3,730 total dosages of methylphenidate, 246 total dosages of buprenorphine, 13,301 total dosages of oxycodone, 20,358 total dosages of hydrocodone, and 2,160 total dosages of fentanyl base. Overall this is a difference of 6,161 total dosages.

9. Quotas: N/A.

DRUG AND EQUIPMENT SECURITY

11. PUBLIX is located in an industrial park area on the south side of Orlando, Florida. The firm is the only tenant, occupying 241,783 square feet, of a building equipped with a 35 foot ceiling. The building is constructed of tilted poured concrete panels with a metal corrugated roof. The warehouse area consists of 231,779 square feet and the remaining

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square footage is designated as office space. The building is equipped with a mezzanine, which accounts for 54,409 square feet of the warehouse area and 7,355 square feet of the office area. This area is considered to be a low crime area. The Orange Co. Sheriff's Office is the responding law enforcement agency.

12. The firm's location is surrounded by a 10 foot galvanized chain link fence capped with barbed wire. The main entrance onto the property is through a security gate equipped with an intercom system. The intercom system is operated by the firm's security team. Visitors are identified and validated by the appropriate distribution center associate, prior granting access onto the property. Exterior cameras provide the security team with the ability to observe the visitor(s) from the perimeter entry gate to the main entrance to the building. Exterior lighting is present on the building and parking area. The firm has approximately 22 cameras to monitor and record exterior activities. Monitoring of the camera views and alarms are conducted at the 24/7 security office located on-premises. The recordings are archived for a 60 day period. Access to the building and specific areas are restricted by the use of an electronic key card system. If warranted, the firm can obtain a detailed report regarding the use of these key cards. Additionally, security team members conduct patrols and are equipped with radios for communication.

13. The main entrance to the building, which is a single glass panel door enclosed in a metal frame, is located on the east wall. This door is surrounded by glass panels enclosed in metal frames. This area is equipped with two glass breakage sensors. The east wall also consists of four exterior doors and eighteen metal overhead doors. The main entrance is utilized by all visitors and employees. The south wall consists of two exterior doors. The north wall has four exterior doors. The west wall consists of three exterior doors and nine metal overhead doors. All exterior doors, including the metal overheard doors, are equipped with a magnetic contact switches. Additionally, exterior cameras record and monitor these exterior doors.

14. The main entrance opens to an enclosed lobby area equipped with an enclosed reception window. The reception window is manned by the firm's security teams. All visitors are required to present identification, log in, obtain a visitor's badge and be escorted by an employee.

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15. The warehouse area and office area are separated by interior doors equipped with the electronic key card and a magnetic contact switch. Access is restricted to only authorized personnel. There are a total of 12 long range motion detectors located throughout the interior of the firm. Additionally, the firm has approximately 85 internal cameras located in the warehouse area.

16. Schedule 2 controlled substances are stored in a UL rated Class M, five sided modular vault purchased and installed by VSI Vault Structures, 3640 Work Drive, Fort Myers, Florida. The vault occupies 4,480 square feet of the firm's warehouse area. The east wall of the vault has two Class M vault door, one measuring 144.5"H x 96 ¼"'W Class M vault doors, which listed identification information: Class M, No. AOO# 292093, 12-31-2015 and the other measuring 78"H x 37"W, which listed identification information: Class M, No. AOO# 292094, 12-31-2015. Both of these doors utilize two Kaba Mas (Mas Hamilton) U.L. Listed Group 1A electronic Lock and are furnished with a self- closing, self-locking mesh day gate equipped with a magnetic contact switch. Additionally, there is an emergency exit Class M vault door measuring 78"H x 37"W, located on the north wall of the vault. This door is equipped with an interior emergency release and has no exterior lock or handle. This door listed identification information Class M, No. AOO# 292095, 12-31-2015. The vault is equipped with 22 cameras and 4 motion detectors.

17. Schedule 3-5 controlled substances are stored inside a WireCrafters 840 Series cage, which occupies 8,960 square feet of the warehouse. The cage is constructed 2" x 1" rectangular woven 10 gauge wire mesh welded to 1 ¼" x 1 ¼" x 1/8 angle frame. The cage is mounted on 2" x 2"x 14 gauge steel tube posts. Base plates of 2" x 7" x ¼" steel flat with two 7/16" round holes for anchoring are welded to each tube. The steel posts are secured by bolts which are fastened to the concrete floor and ceiling. The west wall of the cage is bolted to the firm's vault. All other walls and doors of the cage are of the same material. The panels and posts are brazed, pinned and tack welded in place. The cage has two single self-closing and self-locking doors of the same material. Additionally, there is an automatic self-closing and self-locking double width door of the same material. All doors are protected with magnetic contact switches. The cage is equipped with six motion detectors and with 22 cameras.

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18. The firm's alarm system was installed and is monitored by Tyco Integrated Security LLC, 10500 University Center Drive, Tampa, Florida 33612. The alarm system consists of a Bosch B440 Cellular Communicator as the primary means of communication accompanied by Telguard TG7 Cellular communicator. If an alarm or failure in communication occurs, the alarm company contacts the firm and law enforcement. Additionally, both systems are constantly supervised by the firm's on-site burglar alarm panel, which is manned by the firm's security personnel 24/7. The alarm panel initiates both an audible and visual alarm. In the event of power failure, the firm has a full capacity on-site generator to power the entire facility.

19. On September 30, 2019 DI McElhenny and DI Uban conducted an alarm test of the system. All breached devices were correctly identified by the Central Monitoring Station in a timely manner. A copy of the firm's alarm contract with documentation of the results of the test are included as **Enclosure 5.**

20. The following individuals have access to the controlled substances:

NAME	POSITION	DOB LAST SSN
AMEDO, JOSHUA	ORDER CHECKER	[redacted]
ARANGUREN, SEBASTIAN	SELECTOR	
BADIA, ROSALIA	STOCKER	
BONILLA, JONATHAN	DOCK COORDINAT	
BROWN, MARCUS	RECEIVER	
CALDERON, ANGEL	SELECTOR	
CAMPOS, TISHA	ORDER CHECKER	
CHAMNESS, JEREMY	WAREHOUSE	
CRUZ, LUIS	WAREHOUSE	
DAVIS, ALFRED	MOTOR	

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DAVIS, KYLE	DIRECTOR
DICKO, HASSAN	LEAD PERSON
DIEUJUSTE, DIRONEL	DELECTOR
DIXON, THAD	DOCK COORDINATOR
DORSEY, RECO	DOCK COORDINATOR
FEVRY, YVES	ORDER CHECKER
FLEISHER, JOSHUA	ANALYST
FRANCHI, KATIE	WAREHOUSE
GRAHAM, KENNETH	WAREHOUSE
GREEN, CARL	ORDER CHECKER
GRIGGS, ALEXANDER	ANALYST
HAAS, ALEXANDER	SUPERVISOR
HARRIS, QUYANA	MOTOR
HAYNES, DENIESHIA	SELECTOR
HULETT, MELISSA	STOCKER
JACKSON, CANDACE	ANALYST
JENKINS, LEON	LEAD PERSON
JEREMIAH, TIRAS	WAREHOUSE
JOHNSON, MARCUS	ORDER CHECKER
JOHNSON, TAYLOR	SELECTOR
JOHNSON, TERRANCE	SELECTOR
JOSEPH, RICHENA	SELECTOR

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LESTER, MICHAEL	VP
MADRID, ABEL	SELECTOR
MILLER, SANDRA	STOCKER
MOORE, JAMES	SELECTOR
MOORE, MARION	ANALYST
ORTIZ, CHRISTIAN	WAREHOUSE
ORTIZ, MARCO	WAREHOUSE
PEGEESE, TAMIA	WAREHOUSE
PELHAM, WILLIAM	MANAGER
PERRY, WILLIAM	ORDER CHECKER
RADMANOVIC, DEAN	ORDER CHECKER
RADMANOVIC, SMILIJANA	WAREHOUSE
RADMANOVIC, ZELJKO	ANALYST
REYES, KERVIN	WAREHOUSE
RICHBERG, KEVIN	MOTOR
RIVERA, HARRISON	RECEIVER
RODRIGUEZ, ANTHONY	OPERATOR
SANTIAGO, JOHN	SUPERVISOR
SANTIAGO, RAFAEL	MOTOR
SANTOS, JUSTIN	DOCK PERSON
SHAIA, MARK	SUPERINTENDENT
SLONE, LAURA	DEPT. HEAD

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SOMANI, NADIR	SELECTOR	[redacted]
SOTO, LUIS	WAREHOUSE	
ST. LOUIS, JUNIOR	LEAD PERSON	
TELUSMA, GILMANE	SELECTOR	
VASQUEZ, SHAYNA	SELECTOR	
WAGNER, APOLLONIA	ORDER CHECKER	
WHITE, STEVIE	RECEIVER	
WILLIAMS, JOSEPH	ANALYST	
ZUNIC, ENES	SELECTOR	

A NADDIS check revealed no derogatory information.

PUBLIX corporate office conducts all reference and background checks on prospective employees. If successful, the applicant is referred to the corporate office for further review. All employees are subject to random drug screens.

INTELLIGENCE INFORMATION

21. The firm had no information to report concerning trends or other intelligence.

FOREIGN SUPPLIERS AND CUSTOMERS

22. N/A

DISCREPANCIES AND DISCUSSION WITH MANAGEMENT

23. DI McElhenny held a discussion with Ms. SLONE and Ms. RODRIGUEZ. Firm representatives were advised that of the selected records reviewed, no violations were discovered. This case remains open pending review of the firms Suspicious Order Reporting and Due Diligence Files.

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VERIFICATIONS

24. On September 30, 2019, DI McElhenny contacted ADDISON LNU, Corporate Warehouse Expense Analyst, to conduct a verification of controlled substances shipped from PUBLIX SUPER MARKETS, INC. The verification indicated no discrepancies in the quantity of controlled substances received on August 30, 2018, November 16, 2018, and July 07, 2019.

M. SPECIAL ASSIGNMENTS:

25. N/A

INDEXING:

[redacted]

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REPORT OF INVESTIGATION

1. Program Code	2. Cross Related Files File	3. File No. [redacted]	4. G-DEP Identifier [redacted]
5. By: Richard J Albert, DI At:	☐ ☐ ☐ ☐ ☐	6. File Title Publix Super Markets, Inc., Rocket Court Warehouse	
7. ☐ Closed ☐ Requested Action Completed ☐ Action Requested By:		8. Date Prepared 03-17-2021	

9. Other Officers: DI Karen Moreno

10. Report Re: Meeting with Laura SLONE, PUBLIX SUPER MARKETS, INC., ROCKET COURT WAREHOUSE, 10400 Rocket Ct., Orlando, FL 32824; DEA# RP0500391 [redacted]

SYNOPSIS

This case was initiated pursuant to Fiscal Year 2019 Investigative Work Plan for the Miami Field Division, Orlando District Office. PUBLIX SUPER MARKETS, INC. ROCKET COURT WAREHOUSE, is registered with the DEA as a Distributor in Schedule II-V controlled substances at 10400 Rocket Court, Orlando, FL 32824 under DEA# RP0500391, expiration date March 31, 2022.

On March 8, 2021, Diversion Investigator (DI) Richard Albert contacted Senior Healthcare Attorney Adam R. Maingot, via email, to follow-up on question number three. Mr. Maingot provided a response on March 15, 2021, giving detailed information on the difference bewtween PUBLIX old computer system, SOMlink vs the new system, OrderInsite.

On March 17, 2021, DI Albert contacted Mr. Maingot, via email, to follow-up on PUBLIX's due diligence on suspicious orders, to include sample documentation and a detailed explanation of the step-by-step process.

DETAILS

1. This case was initiated pursuant to Fiscal Year 2019 and had remained open pending completion of a review of the firm's due diligence program.

2. On February 16, 2021, Diversion Investigators (DIs) Richard Albert and Karen Moreno traveled to PUBLIX SUPER MARKETS, INC. ROCKET COURT WAREHOUSE (PUBLIX), 10400 Rocket Court, Orlando, FL 32824, DEA# RP0500391, and met

11. Distribution: Division District Other [redacted]	12. Signature (Agent) /s/ Richard J Albert, DI	13. Date 03-17-2021
	14. Approved (Name and Title) /s/ James W Graumlich, GS	15. Date 03-22-2021

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with Pharmacy Department Head Laura SLONE and Senior Healthcare Attorney Adam Maingot. The purpose of the meeting was for the Investigators to provide questions that will produce information on due diligence and suspicious orders for PUBLIX. DI Albert provided Ms. SLOAN with a list of questions relating to operations by PUBLIX on how the firm handles their due diligence procedures. Both Ms. SLONE and Mr. Maingot stated that they would provide this information to the Investigators in the form of an email.

3. On March 1, 2021, DI Albert received an email from Mr. Maingot with responses to the questions that were previously posed by DI Albert. In response to questions asked by DI Albert on February 16, 2021, PUBLIX provided the following responses (**Attachment 1**):

- **Please provide a flow chart describing PUBLIX's Suspicious Order Monitoring Report System.** PUBLIX provided a flow chart that shows events from the time a purchase order is requested by a PUBLIX retail pharmacy to the time the order is sent out to the PUBLIX store. The chart also shows the flow of suspicious orders from the SOM system throughout the compliance process of PUBLIX. The chart is listed as Exhibit 1 in Attachment 1.
- **Please provide a list of all suspicious orders reported to DEA.** PUBLIX provided a list of all suspicious orders sent to the DEA beginning in September 2019 to February 2021. This is provided as Exhibit 2, of Attachment 1.
- **If the system has changed significantly in the last five years, please provide an explanation of differences in the old/new system.** PUBLIX first obtained their DEA registration at Rocket Court in 2016. Since 2016 through July 2020, PUBLIX has interrogated and tracked orders using SOMLink suspicious order monitoring software. In August 2020, a new suspicious order monitoring software, OrderInsite was fully implemented. SOMlink was a system requiring manual setup and maintenance of new stores, as well as, drug groups and thresholds used to identify potential orders of unusual size, frequency, and pattern. OrderInsite provides more automated set-up and maintenance for new stores using similar location model for start-up. It also provides some automation and more flexibility around maintenance of thresholds for drug groups/categories and NDCs. PUBLIX can now

maintain multiple levels of thresholds which they could not do in the old system. PUBLIX has a one day, seven day, and 30 day threshold. This presents opportunities to increase or decrease thresholds for drug groups, as well as single NDCs, which enables PUBLIX to analyze and then approve or decline. The thresholds aid in the detection of orders of interest. From the OrderInsite platform, PUBLIX can access their analytical tools to evaluate the order of interest right from the platform, which makes it much more efficient than the old system which was a stand-alone and required PUBLIX to use different tools to perform their analysis.

- **Who places orders at/for the stores? (Differences in 2's and 3-5's?)** PUBLIX inventory management software generates product request to meet each pharmacy's forecasted demand. In addition, pharmacy associates can manually request product (e.g., new patient arrives after pre-defined product request is generated). Automated product requests consider pending inbound inventory. Pharmacists may review and modify automated and manual product requests before they are transmitted. Requests for CII products are individually reviewed and approved by dedicated CSOS administrators prior to receipt by the warehouse. Once a request is approved, the central reviewer (i.e. CSOS administrator) is the individual who actually issues the order using his/her digital certificate.
- **Based on what information?** Product requests are based on, on-hand inventory and minimum shelf stock inventory required for forecasted demand.
- **Who/What initially reviews the order received by Distributor? How?** Orders are interrogated by the OrderInsite suspicious order monitoring system prior to receipt by Distribution. Any order that is flagged by OrderInsite (i.e., an order of interest) is reviewed and cleared by a pharmacy compliance analyst.
- **Based on what decision process/algorithm?** PUBLIX's Suspicious Order Reports System (SORS) is designed to detect orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. Orders of interest are flagged by OrderInsite when orders (a) exceed anticipated demand (i.e., established thresholds) or (b) are flagged by OrderInsite Analytic Tests (i.e., algorithms) designed to address size, pattern, and frequency.

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- **Who takes what action and how is it documented?** An item flagged by OrderInsite is automatically omitted from the order (i.e., not shipped) without regard to whether it is, in fact, suspicious. It is then queued for review by the pharmacy compliance department as an order of interest. A compliance analyst investigates each order of interest and either (a) confirms the order should be reported as suspicious; or (b) obtains credible evidence to conclude the order is not suspicious. Supporting documentation is maintained in the OrderInsite system, internal network drives, and in a summary case report.
- **What information is reviewed?** The flagged order review considers relevant information which, on a case-by-case basis, may include such things as dispensing history, forecasted demand, min/max order points, current balance on hand, prescription level information, inventory adjustments, store's local market/business evaluation (e.g., formulary change, storm/hurricane, clinic opening/closing, pharmacy acquisition), and industry evaluation (e.g., recalls, shortages), among other data points.
- **Who makes the next decision in chain?** The pharmacy compliance department will determine if flagged orders are is suspicious or not.
- **If an order is determined to not be suspicious, what happens?** The requesting pharmacy or the pharmacy compliance department may issue a second request for the product because the initial order of interest was omitted/killed without regard to whether it was suspicious.
- **If an order is determined to be suspicious, what happens?** All orders deemed suspicious will be reported to the DEA. The flagged item would have already been omitted from the order and the item would not have been shipped.
- **Who takes what action to notify DEA? How?** The pharmacy compliance department prepares the DEA notification in the DEA's SORS system.
- **Can an order be determined to be suspicious and not reported to DEA?** No, PUBLIX's policy is to report orders deemed suspicious.

4. **Information of PUBLIX's Shipping System**

- **How is an order received?** Orders are electronically received into the warehouse management system.

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- **How is an order picked/checked/packaged?** First, the order is sent to the selector's vocollect headset via inventory management software (Dallas - WMS). Then, the selector picks and places the products ordered in the tote. Next, the tote is staged for quality control. During the quality control process, order checkers reconcile the products in the tote against the order using a handheld scanning tool. Once the CII order passes quality control, the products are placed in a tamper-resistant sealed bag and the tote is closed with the tote ties. CIII-V's follow a similar quality control process. Once the CIII-V order passes quality control, the tote is closed with the tote ties and all CIII-V sealed totes are stated to be merged with shipping pallets.
- **How is the tote secured/transported?** Totes are secured with serializes tote ties under camera within the designated controls area (e.g., cage or vault). The totes are scanned out of the warehouse (for creation of the advanced shipment notice file) and promptly placed on the receiving courier's trailer for distribution to the destination pharmacy.
- **How is the tote different from other non-c/s totes?** Totes containing controlled substances do not differ from totes that do not contain controlled substances (e.g., no specific colors or markings).
- **How is the tote delivered to store?** Totes are delivered by courier.
- **How is the tote received at store?** Serialized tote ties and labels are scanned into the Rx receiving application at the store. The manifest is reviewed, discrepancies noted (if any), initialed, and dated. The product within each tote is scanned into the Rx receiving application.
- **Who signs/Who checks it in?** Pharmacist and/or pharmacy technician can scan in totes and sign manifest. Only the pharmacist can scan and receive controlled substance products.
- **How is it documented?** All tote and product level receiving is documented with user-IDs and time stamps and stored in a database.

5. The attached response letter contains SORS information sent to DEA as Exhibit 2. Information provided by PUBLIX showed 35 suspicious orders reported to DEA since September 13, 2019.

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6. Additional information on PUBLIX's due diligence has been requested and will be documented in a future report. This case remains open.

ATTACHMENT

1. Response Letter dated March 1, 2021

INDEXING

[redacted]

March 15, 2021

U.S. Drug Enforcement Administration
Orlando District Office, Diversion Control Group
c/o Diversion Investigator Richard J. Albert
300 International Parkway, Suite 424
Heathrow, FL 32746

Publix Super Markets, Inc.
Rocket Court Warehouse
10400 Rocket Court
Orlando, FL 32824
DEA # RP0500391

RE: 2019 Publix Warehouse DEA Inspection – First amended and restated follow up questions.

Dear DI Albert:

On March 1, 2021, Registrant RP0500391 submitted written responses to questions posed by DEA on February 16, 2021, in connection DEA's September 2019 on-site inspection of the Registrant. On March 8, 2021, DEA requested additional clarification on Publix's March 1, 2021 response to Q1.3, *re: significant changes to Publix's SOM system*. The following first amended and restated response letter (i) provides the requested clarification to Q1.3; (ii) contains an updated / corrected Exhibit B with the latest orders reported to the DEA SORS; and (iii) is intended to replace Publix's March 1, 2021 response letter.

Section 1. Publix SORS.

Q1.1: [Please provide a flow chart describing Publix's Suspicious Order Monitoring/Report System].

R1.1: Please see Exhibit 1 (Publix SORS Flow Chart).

Q1.2: [Please provide a list] of all suspicious orders reported to DEA.

R1.2: Please see Exhibit 2 (Publix SORs reported since last DEA inspection).

Q1.3: If system has changed significantly in last 5 years, please provide an explanation of differences in old/new system.

R1.3: The Registrant first obtained its DEA Registration at this location in 2016. Since the initial Registration date through July 2020, the Registrant interrogated and tracked orders using the SOMLink suspicious order monitoring software. In August 2020, a new suspicious order monitoring software, OrderInsite, was fully implemented. SOMlink was a system requiring manual setup and maintenance of new stores, as wells as, drug groups and thresholds used to identify potential orders of unusual size, frequency, and pattern. OrderInsite provides more automated set up and maintenance for new stores using a similar location model for start-up. It also provides some automation and more flexibility around

the maintenance of thresholds for drug groups/categories and NDCs. We can now maintain multiple levels of thresholds which we couldn't do in our old system. We have a 1-day, 7-day and 30-day threshold. It will present opportunities to increase or decrease thresholds for drug groups, as well as single NDCs, which we can analyze and then approve or decline. The thresholds aid in the detection of orders of interest. From the OrderInsite platform, we can access our analytical tools to evaluate the order of interest right from the platform – it's much more efficient than our old system which was stand alone and required us to use different tools to perform our analysis.

Q1.4: Who places orders at/for stores? (Difference in 2s and 3-5s).

R1.4: Publix inventory management software generates product requests to meet each pharmacy's forecasted demand. In addition, pharmacy associates can manually request product (e.g., new patient arrives after a pre-defined product request is generated). Automated product requests consider pending inbound inventory. Pharmacists may review and modify automated and manual product requests before they are transmitted. Requests for CII products are individually reviewed and approved by dedicated CSOS admins. prior to receipt by the warehouse. Once a request is approved, the central reviewer (i.e., CSOS admin.) is the individual who actually issues the order using his/her digital certificate.

Q1.5: Based on what information?

R1.5: Product requests are based on on-hand inventory and minimum shelf stock inventory required for forecasted demand.

Q1.6: How is order placed?

R1.6: See R1.4

Q1.7: Who/What initially reviews order received by Distributor? How?

R1.7: Orders are interrogated by the OrderInsite suspicious order monitoring system prior to receipt by Distribution. Any order that is flagged by OrderInsite (i.e., an order of interest) is reviewed and cleared by a pharmacy compliance analyst. See R1.1, R1.4. See R1.4 & R1.8.

Q1.8: Based on what decision process/algorithm?

R1.8: Publix's SORS is designed to detect orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. Orders of interest are flagged OrderInsite when

orders (a) exceed anticipated demand (i.e., established thresholds) or (b) are flagged by OrderInsite Analytic Tests (i.e., algorithms) designed to address size, pattern, and frequency. See R1.1.

Q1.9: Who takes what action and how is it documented?

R1.9: An item flagged by OrderInsite is automatically omitted from the order (i.e., not shipped) without regard to whether it is, in fact, suspicious. It is then queued for review by the Pharmacy Compliance Department as an order of interest. A compliance analyst investigates each order of interest and either (a) confirms the order should be reported as suspicious; or (b) obtains credible evidence to conclude the order is not suspicious. Supporting documentation is maintained in the OrderInsite system, internal network drives, and in a summary case report. See R1.1, R1.12.

Q1.10: If order is tagged what review is done?

R1.10: See R1.9.

Q1.11: By Whom?

R1.11: See R1.9.

Q1.12: What information is reviewed?

R1.12: The flagged order review considers relevant information which, on a case-by-case basis may include such things as dispensing history, forecasted demand, min/max order points, current balance on hand, prescription level information, inventory adjustments, store's local market/business evaluation (e.g., formulary change, storm/hurricane, clinic opening/closing, pharmacy acquisition), and industry evaluation (e.g., recalls, shortages), among other data points.

Q1.13: Who makes next decision in chain?

R1.13: Pharmacy Compliance Department will determine if flagged order is suspicious or not.

Q1.14: If order is determined to be not suspicious what happens?

R1.14: The requesting pharmacy or the Pharmacy Compliance Department may issue a second request for the product because the initial order of interest was omitted / killed without regard to whether it was suspicious.

Q1.15: If order is determined to be suspicious what happens?

R1.15: All orders deemed suspicious should be reported to the DEA. The flagged item has already been omitted from the order and the item was not shipped.

Q1.16: Who takes what action to notify DEA? How?

R1.16: The Pharmacy Compliance Department prepares the DEA notification in the DEA's SORS See R1.1.

Q1.17: Can an order be determined to be suspicious and not be reported to DEA?

R1.17: No, Publix's policy is to report orders deemed suspicious.

Q1.18: Under what circumstances?

R1.18: Not applicable. See R1.17.

Q1.19: Who reviews?

R1.19: Not applicable. See R1.17.

Q1.20: Who decides?

R1.20: Not applicable. See R1.17.

Q1.21: How documented?

R1.21: Not applicable. See R1.17.

Section 2. Publix Shipping System:

Q2.1: How is order received?

R2.1: Orders are electronically received into the warehouse management system.

Q2.2: How is order picked/checked/packaged?

R2.2: First, the order is sent to the selector's vocollect headset via inventory management software (Dallas - WMS). Then, the selector picks and places the products ordered in the tote. Next, the tote is staged for quality control. During the quality control process, order checkers reconcile the products in the tote against the order using a handheld scanning tool. Once the CII order passes quality control, the products are placed in a tamper-resistant sealed bag and the tote is closed with the tote ties. CIII-V's follow a similar quality control process. Once the CIII-V order passes quality control, the tote is closed with the tote ties and all CII-V sealed totes are staged to be merged with shipping pallets.

Q2.3: How is tote secured/transported?

R2.3: Totes are secured with serialized tote ties under camera within the designated controls area (e.g., cage or vault). The totes are scanned out of the warehouse (for creation of the advanced shipment

notice file) and promptly placed on the receiving courier's trailer for distribution to the destination pharmacy.

Q2.4: How is tote different from other non-c/s totes?

R2.4: Totes containing controlled substances do not differ from totes that do not contain controlled substances (e.g., no specific colors or markings).

Q2.5: How is tote delivered to store?

R2.5: Totes are delivered by courier.

Q2.6: How is it received at store?

R2.6: Serialized tote ties and labels are scanned into the Rx receiving Application at the store. The manifest is reviewed, discrepancies noted (if any), initialed, and dated. The product within each tote is scanned into the Rx Receiving application.

Q2.7: Who signs/Who checks it in?

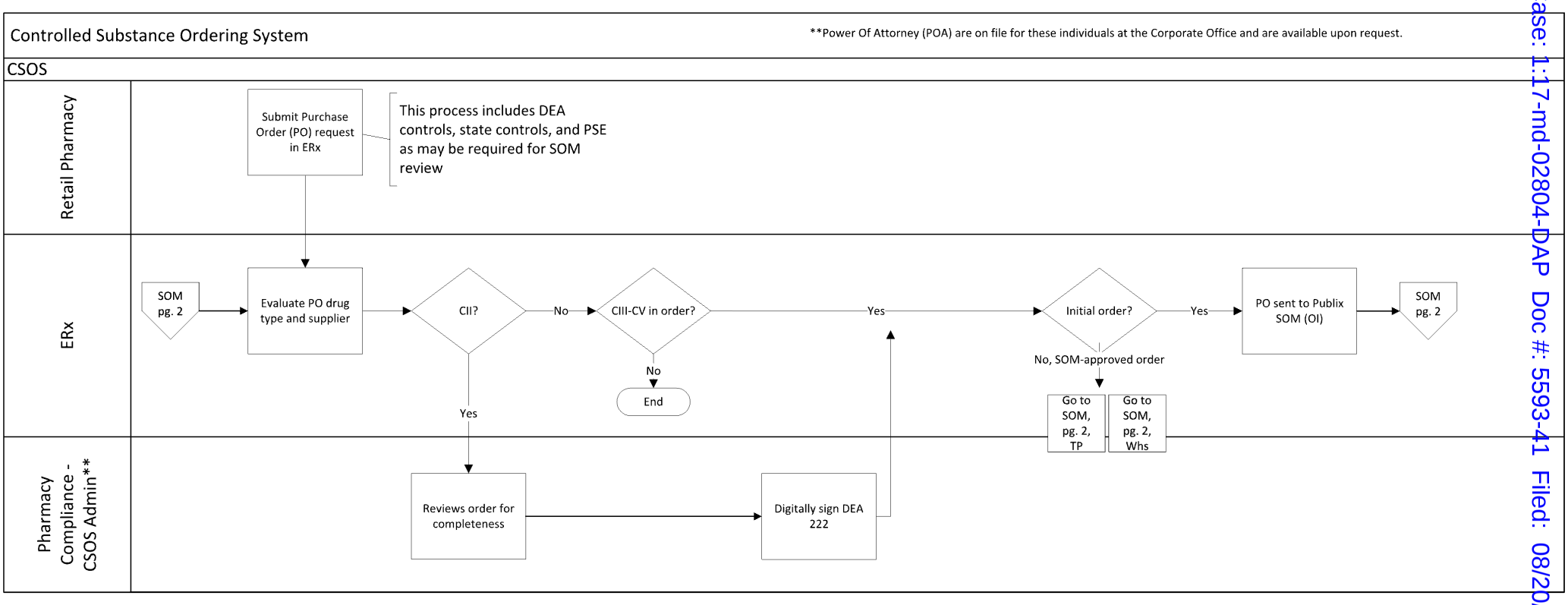
R2.7: Pharmacists and/or Pharmacy Technicians can scan in totes and sign manifests. Only the Pharmacist can scan and receive controlled substance products.

Q2.8: How and How documented?

R2.8: All tote and product level receiving is documented with user-IDs and time stamps and stored in a database.

Exhibit 1

SORS Flow Chart



Suspicious Order Monitoring Program

SOM System

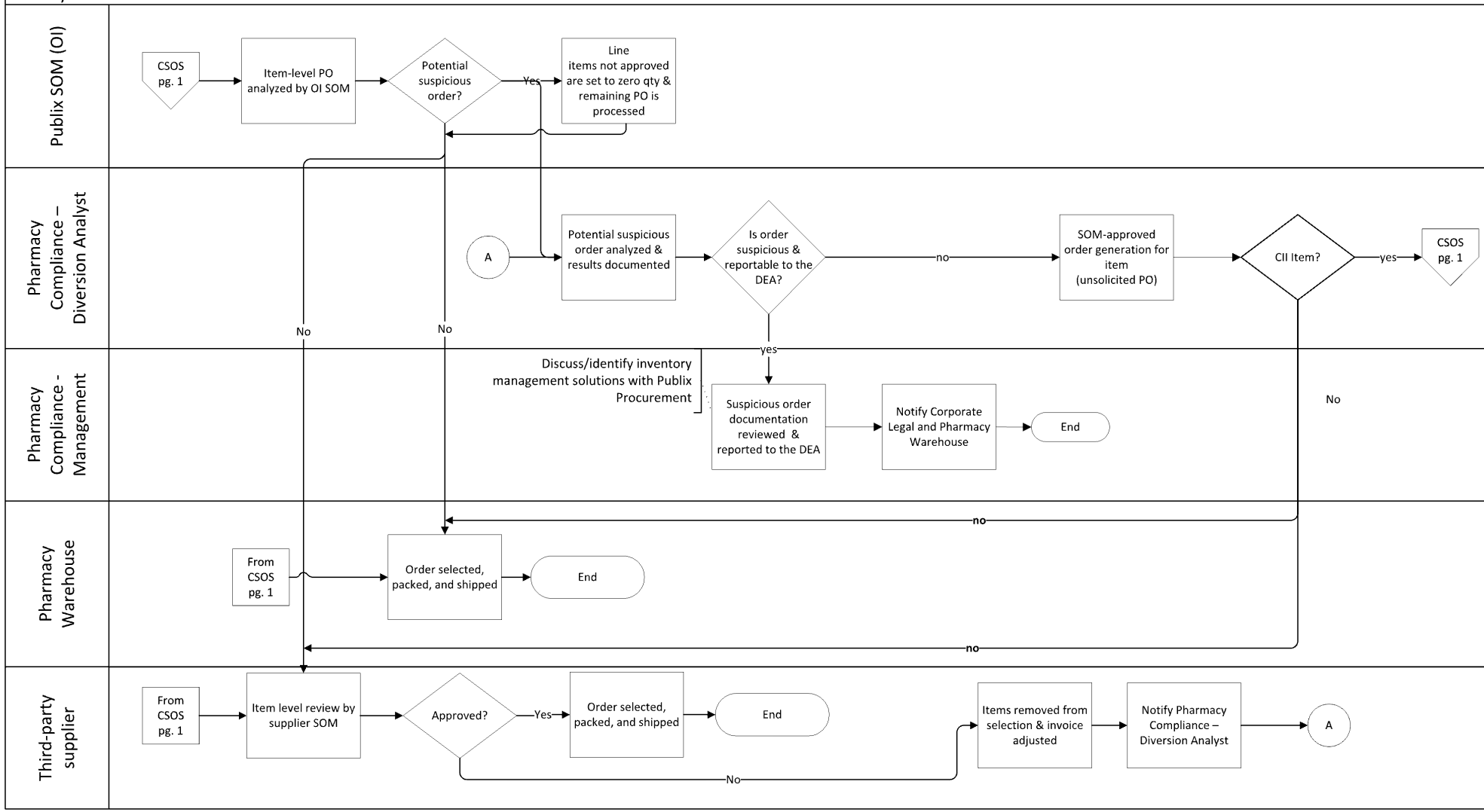


Exhibit 2

SORs Filed Since Last DEA Inspection (9/19)

Order Date	Ordering Pharmacy	Product	Strength	Order #	NDC	Quantity Order	Quantity supplied
9/13/2019	Publix #1129 15000 Miami Lakes Dr., E., Miami, FL 33014	Oxycodone	30 MG tabs	19X107132	47781026501	11	3
9/27/2019	Publix # 1371 3863 S US HWY 301 Riverview, FL 33578	Oxycodone	30 MG tabs	19X113158	47781026501	10	5
10/7/2019	Publix # 1371 3863 S US HWY 301 Riverview, FL 3357	Oxycodone	30 MG tabs	19X116998	47781026501	12	8
10/16/2019	Publix # 1371 3863 S US HWY 301 Riverview, FL 33578	Oxycodone	30 MG tabs	19X121178	47781026501	10	5
10/29/2019	5997 S Pointe Blvd., Suite 106 Fort Myers, FL 33919	Oxycodone	30 MG tabs	19X127204	47781-0265-01	16	12
11/7/2019	5997 S Pointe Blvd., Suite 106 Fort Myers, FL 33919	Oxycodone	30 MG tabs	19X131376	47781-0265-01	14	10
11/19/2019	5997 S Pointe Blvd., Suite 106 Fort Myers, FL 33919	Oxycodone	30 MG tabs	19X136176	47781-0265-01	13	10
11/29/2019	101 N. Blairstone Rd., Ste 301 Tallahasee, FL 32301	Methadone	10MG tabs	19X140062	13107-0889-01	11	0
12/10/2019	101 N. Blairstone Rd., Ste 301 Tallahasee, FL 32301	Methadone	10 MG tabs	19X144341	13107-0089-01	10	3
12/17/2019	8701 W. Hillsborough Ave., Tampa, FL 33615	Oxycodone	30 MG tabs	19X127204	47781-0265-01	10	8
6/08/2020	3900 66th St. N., Saint Petersburg, FL 33709	Phentermine	37.5mg tabs	9365	11534-0160-01	4	0
6/13/2020	1033 A1A Beach Blvd., St Augustine, FL 32080	Buprenorphine	8mg sub tabs	15615	00228-3153-03	3	0
6/13/2020	1033 A1A Beach Blvd., St Augustine, FL 32080	Buprenorphine/Nalaxone	8-2mg sub tabs	15615	00228-3153-03	4	0
6/13/2020	1033 A1A Beach Blvd., St Augustine, FL 32080	Buprenorphine	8mg sub tabs	15615	00228-3153-03	3	0
6/11/2020	4900 Atlanta Hwy, Alpharetta, GA 30004	Buprenorphine	8mg sub tabs	14967	00228-3153-03	4	0
10/10/2020	2153 E Main St., Duncan, SC 29334	Butorphanol Nasal Spray	10mg/ml nasal spray	15702	00054-3090-36	2	0
10/12/2020	2153 E Main St., Duncan, SC 29334	Butorphanol Nasal Spray	10mg/ml nasal spray	15709	00054-3090-36	2	0
11/1/2020	2153 E Main St., Duncan, SC 29334	Butorphanol Nasal Spray	10mg/ml nasal spray	15766	00054-3090-36	3	0
11/7/2020	2153 E Main St., Duncan, SC 29334	Butorphanol Nasal Spray	10mg/ml nasal spray	15796	00054-3090-36	2	0
11/8/2020	2153 E Main St., Duncan, SC 29334	Butorphanol Nasal Spray	10mg/ml nasal spray	15799	00054-3090-36	1	0

Order Date	Ordering Pharmacy	Product	Strength	Order #	NDC	Quantity Order	Quantity supplied
11/15/2020	2153 E Main St., Duncan, SC 29334	Butorphanol Nasal Spray	10mg/ml nasal spray	15818	00054-3090-36	1	0
11/16/2020	2153 E Main St., Duncan, SC 29334	Butorphanol Nasal Spray	10mg/ml nasal spray	15823	00054-3090-36	1	0
11/17/2020	11352 N Williams St., Ste 400, Dunnellon, FL 34432	Fentanyl Patch	25 MCG	20X14054302516	47781-0424-47	6	0
11/18/2020	2153 E Main St., Duncan, SC 29334	Butorphanol Nasal Spray	10mg/ml nasal spray	15832	00054-3090-36	2	0
11/21/2020	2153 E Main St., Duncan, SC 29334	Butorphanol Nasal Spray	10mg/ml nasal spray	15839	00054-3090-36	2	0
1/2/2021	2153 E Main St., Duncan, SC 29334	Butorphanol Nasal Spray	10mg/ml nasal spray	15865	00054-3090-36	3	0
1/4/2021	2153 E Main St., Duncan, SC 29334	Butorphanol Nasal Spray	10mg/ml nasal spray	15972	00054-3090-36	5	0
1/6/2021	2153 E Main St., Duncan, SC 29334	Butorphanol Nasal Spray	10mg/ml nasal spray	15679	00054-3090-36	5	0
1/18/2021	2153 E Main St., Duncan, SC 29334	Butorphanol Nasal Spray	10mg/ml nasal spray	16019	00054-3090-36	4	0
1/23/2021	2153 E Main St., Duncan, SC 29334	Butorphanol Nasal Spray	10mg/ml nasal spray	16041	00054-3090-36	1	0
1/24/2021	2153 E Main St., Duncan, SC 29334	Butorphanol Nasal Spray	10mg/ml nasal spray	16043	00054-3090-36	1	0
1/28/2021	2153 E Main St., Duncan, SC 29334	Butorphanol Nasal Spray	10mg/ml nasal spray	16061	00054-3090-36	1	0
2/3/2021	3750 Roscommon Dr., Ormond Beach, FL 32174	Alprazolam	1mg	13791	00228-2031-10	3	0
3/10/2021	1501 NW Federal Hwy Stuart FL 34994	Morphine Sulfate ER	100mg tab	21X02758908029	42858-0804-01	2	0
3/11/2021	1620 Blowing Rock Rd Boone, NC 28607	Oxycodone	30mg tab	21X02788903561	47781-0265-01	1	0

April 9, 2021

U.S. Drug Enforcement Administration
Orlando District Office, Diversion Control Group
c/o Diversion Investigator Richard J. Albert
300 International Parkway, Suite 424
Heathrow, FL 32746

Publix Super Markets, Inc.
Rocket Court Warehouse
10400 Rocket Court
Orlando, FL 32824
DEA # RP0500391

RE: 2019 Publix Warehouse DEA Inspection – Response to DI Albert's March 17, 2021 email.

Dear DI Albert:

On March 16, 2021, Registrant RP0500391 submitted written responses to questions posed by DEA on March 8, 2021, in connection DEA's September 2019 on-site inspection of the Registrant. On March 17, 2021, DEA: (i) requested additional clarification on Publix's March 16, 2021 responses to Q1.7 *re: the SOM review process* and Q1.9 *re: evidence to clear orders of interest*; and (ii) asked two additional questions labeled as Q1.21 *re: Publix's SORS reporting* process and Q1.22 *re: flagged orders of interest ultimately cleared as not suspicious.* The following responses to Q1.7, 1.9, 1.21, and 1.22 are intended to supplement Publix's March 16, 2021 response letter.

Section 1. Publix SORS.

Q1.7.1: Provide step-by-step documentation on how an order flagged by OrderInsite is reviewed and cleared by a pharmacy compliance analyst.

R1.7.1: Step 1. OrderInsite has the ability to flag entire pharmacy medication requests or individual product line items within the request. Assuming we are dealing with a multi-product request, an individual product line item of interest is flagged by OrderInsite, pended for further review (i.e., prevented from shipping), and placed within a work queue for due diligence.

Fig.1.7.1.1 OrderInsite work queue containing requests

Fig.1.7.1.2 OrderInsite line item (highlighting indicates removed from request (e.g., ordered/received quantity 0))

Attachment 1 [redacted] 04/15/2021

Step 2. The Publix Controlled Substance Compliance Analyst ("Analyst") treats each queued line item (each a request for a medication product) as a request for order received under suspicious circumstances ("RFORUSC"), whether or not such request qualified as an Order under 21 U.S.C. Ch. 13, et seq.

Step 3. The Analyst promptly conducts due diligence to investigate each suspicious circumstance surrounding the RFORUSC. Since the circumstances for each RFORUSC vary, the diligence process may differ with each request. Common investigative themes include review of internal data points, conversations with relevant Publix personnel, and examination of additional relevant information to determine whether the requesting pharmacy is engaged in, or likely to be engaged in, diversion of controlled substances. See R1.9.1

Step 4. The Analyst records relevant RFORUSC due diligence information in OrderInsite.

Step 5. (a) If each suspicious circumstance surrounding the RFORUSC is resolved, the Analyst updates the "Approved Package" field in OrderInsite and a subsequent request for the approved product line item quantity will be issued by the requesting pharmacy for fulfillment.

(b) If each suspicious circumstance surrounding the RFORUSC is not resolved, the RFORUSC is deemed suspicious and reported to DEA using the DEA online SORS system.

Q1.9.1: For R1.9, who takes what action and how is it documented? Part B says that Publix obtains credible evidence to conclude the request is not suspicious. Supporting documentation is maintained in the OrderInsite system, internal network drives, and in a summary case report. Please provide examples of the supporting documentation and what was used. What makes the evidence credible?

R1.9.1: The Analyst reviews and analyzes information in OrderInsite, the EnterpriseRx pharmacy management system, as well as other data repositories as needed. The Analyst also gathers other pertinent information about the business or market as needed to investigate each suspicious circumstance surrounding the RFORUSC.

Initial analysis involves evaluating datapoints to determine if the requested item is related to a legitimate prescription – either refills or new patients. This includes evaluating the usage of the drug and the dispensing patterns at that location. If dispensing has increased, the analyst determines if it's due to a new pt. or refills and reviews new Rxs or refill Rxs and timing accordingly (considering changes from/to 90-day supplies from/to 30-day supplies also). If dispensing has not increased or has declined, the analyst reviews the centralized inventory forecast and product specific inventory thresholds (min/max) to ensure those are set properly, determines whether the system generated the request or if a manual request had been placed, and evaluates inventory adjustments. During this process, the analyst may determine the requested item in the requested quantity is legitimate and therefore not considered suspicious; at which time they will document and close the case. If the analyst still questions the legitimacy of the request item, they will move on to further analysis.

If further analysis is needed, various information and data is used to determine if a requested item is suspicious or not. This additional evaluation may include pulling more detailed drug usage reports for the facility to identify other patients or prescribers that may be of interest; overall controlled substance dispensing percentages and data points; location growth patterns; market activity (e.g., opening/closing of competitors or clinics); DEA reporting activity (e.g., past 106s, suspicious requests) – just to name a few. If each suspicious circumstance surrounding the RFORUSC is not resolved, the RFORUSC is deemed suspicious and reported to DEA using the DEA online SORS system and a separate investigation is opened to evaluate potential diversion.

Supporting documentation is maintained in OrderInsite as mentioned in R1.7.1 above and may end there if the request is deemed not suspicious based on the initial analysis. If further data and research is completed, this information is saved in an online file for that facility which most often contains excel files containing key data points and commentary as appropriate.

Q1.21: How exactly do you report to the DEA? The step-by-step process, the system that Publix uses, who reports?

R1.21: The Analyst data enters information about the suspicious request on the DEA SORS website. See https://www.deadiversion.usdoj.gov/sors/index.html; see also R1.7.1.

Q1.22: I received a list of 35 SORS filed since September 2019. (a) Those 35 were out of how many flagged during that time frame? (b) How many were reviewed? (c) Could you provide examples of at least 10 requests that were flagged by your system as suspicious and that were shipped? (d) What allows Publix to go-ahead and ship the request? (e) What stops Publix from shipping that request? (f) How does the review of flagged requests work? (g) What steps does the pharmacy compliance analyst take once an request is suspicious/flagged?

R1.22: (a),(b) 18,860 product line item requests from the Publix Pharmacy Warehouse were flagged by the Publix SOM in operation during the relevant time frame. To the best of our knowledge each of the 18,860 flagged items was treated as a RFORUSC and reviewed by an Analyst.

(c) To the best of our knowledge, no items deemed suspicious were shipped. Exhibit 1, attached below, contains data related to ten (10) items which were (i) flagged by Publix's SOM system for investigation (i.e., a RFORUSC); (ii) reviewed by an Analyst; (iii) determined not to be suspicious; and (iv) cleared for shipment.

(d) An RFORUSC is determined not to be suspicious (i.e., appropriate for shipment) when the Analyst determines in good faith that each suspicious circumstance surrounding the RFORUSC has been resolved.

(e) An RFORUSC is automatically (i.e., systematically) stopped from shipping by Publix's OrderInsite system. The RFORUSC remains a pended request until an Analyst determines in good faith that each suspicious circumstance surrounding the RFORUSC has been resolved.

(f), (g) See R.1.7.1; 1.9.1

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U.S. Department of Justice
Drug Enforcement Administration

REPORT OF INVESTIGATION

1. Program Code	2. Cross Related Files File	3. File No. [redacted]	4. G-DEP Identifier [redacted]
5. By: Richard J Albert, DI At:	☐ ☐ ☐ ☐ ☐	6. File Title Publix Super Markets, Inc., Rocket Court Warehouse	
7. ☒ Closed ☐ Requested Action Completed ☐ Action Requested By:		8. Date Prepared 10-12-2021	

9. Other Officers: Group Supervisor James Graumlich

10. Report Re: Case Closing; PUBLIX SUPER MARKETS, INC., ROCKET COURT WAREHOUSE, 10400 Rocket Ct, Orlando, FL 32824; DEA# RP0500391 [redacted]

SYNOPSIS

This case was initiated pursuant to Fiscal Year 2019 Investigative Work Plan for the Miami Field Division, Orlando District Office. PUBLIX SUPER MARKETS, INC. ROCKET COURT WAREHOUSE, is registered with the DEA as a Distributor in Schedule II-V controlled substances at 10400 Rocket Court, Orlando, FL 32824 under DEA# RP0500391, expiration date March 31, 2022.

On September 9, 2021, Diversion Investigator (DI) Richard Albert received a telephone call from Senior Healthcare Attorney Adam Maingot. Mr. Maingot stated that he and his team were gathering responses to an email that DI Albert had previously sent on August 31, 2021. The email requested additional information concerning PUBLIX's due diligence on their individual customer/pharmacy. On that same day, Mr. Maingot sent an email to DI Albert requesting a conference call with DI Albert and Group Supervisor (GS) James Graumlich, to talk through their responses.

On October 8, 2021, a conference call took place with DI Albert, GS Graumlich, Mr. Maingot, and Director-Regulatory Legal William (Bill) Hammond.

DETAILS

1. This case was initiated pursuant to Fiscal Year 2019 and had remained open pending completion of a review of the firm's due diligence program.

11. Distribution: Division District Other [redacted]	12. Signature (Agent) /s/ Richard J Albert, DI	13. Date 10-12-2021
	14. Approved (Name and Title) /s/ James W Graumlich, GS	15. Date 10-15-2021

DEA SENSITIVE
Drug Enforcement Administration

REPORT OF INVESTIGATION (Continuation)	1. File No. [redacted]	2. G-DEP Identifier [redacted]
	3. File Title: Publix Super Markets, Inc., Rocket Court Warehouse	
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5. Program Code	6. Date Prepared: 10-12-2021	

2. On October 8, 2021, DI Albert and GS Graumlich had a conference call with Mr. Maingot and Mr. Hammond. The purpose of the conference call was to address previous questions sent by DI Albert on August 31, 2021. Mr. Maingot requested a conference call to go over the questions to ensure that he would responded correctly and that PUBLIX was in compliance with the Drug Enforcement Administrations' (DEA) request for due diligence as it relates to PUBLIX's warehouse. Mr. Maingot went through each of the questions and both he (Maingot) and GS Graumlich discussed each question.

3. At the end of the call, DI Albert requested the answers to the questions in writing via email. On October 12, 2021, Mr. Maingot sent the responses to the questions via email (**Attachment 1**).

- Who reviews the information on the individual pharmacies and how often? PUBLIX's Corporate Compliance and Records Management (CCRM) department reviews information on the individual pharmacies in response to an observation, referral, or other event of interest. CCRM may seek assistance with reviews from one or more other departments when appropriate, such as Publix Legal, Internal Audit, and Loss Prevention. CCRM is independent of the retail pharmacy operations function and reports to PUBLIX's Chief Compliance Officer.
- What data can you provide on individual pharmacies, ex. Prescription data, red flag data, etc.? CCRM can access pharmacy ordering, dispensing, adjustment, prescriber, patient, and prescription data. An example was given in PUBLIX's June 29, 2021, response letter covering a suspicious order traced to a physician writing fraudulent zolpidem prescriptions which PUBLIX had reported to DEA.
- Does PUBLIX have any other suppliers of controlled substances? Yes, although PUBLIX's pharmacy inventory management systems identify its central Orlando Warehouse registrant as the primary supplier to PUBLIX's retail pharmacy registrants resulting in orders primarily fulfilled by the Orlando Warehouse registrant. Where the Orlando Warehouse registrant is unable to fulfill an order, orders may be fulfilled by independent, third party wholesale distributor AmerisourceBergen (ABC). All controlled substance orders placed on behalf of the pharmacies are processed through PUBLIX's inventory management system and factored into the pharmacy's ordering

activity/history for purposes of the Orlando Warehouse registrant's SOM reviews.

- You spoke about benchmarking, does PUBLIX ever look back at benchmarking? Benchmarks are used each time a PUBLIX pharmacy is opened/onboarded. Typically, initial thresholds are set based on a comparable store. Once the initial thresholds are established, actual pharmacy ordering and dispensing activity for the newly opened location are continuously monitored against dynamic purchasing thresholds using sophisticated inventory management software known as OrderInsite Replenish. Thresholds are reviewed and adjusted daily based on a rolling thirty-day review.
- Does anyone else look at PUBLIX's pharmacies, an outside agency/company? PUBLIX systems? Any outside verification of your systems? Yes. PUBLIX typically provides controlled substance information on a quarterly and/or annual basis to independent, third-party controlled substance suppliers for review. Currently, ABC receives data quarterly. The information typically focusses on retail pharmacy data (i.e., individual Orlando Warehouse's customers). From time to time, we also may engage an outside resource to provide privileged legal advice in connection with state and/or federal controlled substances laws.
- Does PUBLIX look at controls vs non-controls? If so, what is the requirement, if any? Yes, CCRM reviews include consideration of a pharmacy's overall controlled substance percentage and/or CII percentage when relevant. For example, the inquiries into store numbers 1440 and 1500 was nearly a full percentage point below the overall average CII percentage of PUBLIX stores within those locations' same class of trade.
- Does PUBLIX run data/reports on orders of interest? Yes
- How are orders of interest resolved? Orders of interest review considers relevant information which, on a case-by-case basis, can include dispensing history, forecasted demand, min/max order points, current balance on hand, prescription level information, inventory adjustments, store's local market/business evaluation (e.g., formulary change, storm/hurricane, clinic opening/closing, pharmacy acquisition), and industry evaluation (e.g., recalls, shortages), as well as other data points. If the CCRM review determines all suspicious circumstances arising from the order are resolved, the

REPORT OF INVESTIGATION *(Continuation)*	1. File No. [redacted]	2. G-DEP Identifier [redacted]
	3. File Title Publix Super Markets, Inc., Rocket Court Warehouse	
4. **Page 4 of 4**		
5. Program Code	6. Date Prepared 10-12-2021	

order is approved and an order for the product is able to be subsequently re-submitted on behalf of the pharmacy.

- Can you provide a history of Order of Interest for individual stores? What data is used to make decisions (knowing your data is not knowing your customer)? Yes. Regarding data used to make decisions (also in previous response).
- Does PUBLIX look at doctors who had issues with the state? Yes, when relevant, CCRM reviews include consideration of publicly available prescriber discipline from agency websites.
- Who analyzes the sales of controlled substances for the stores? CCRM reviews include analysis of the retail pharmacy locations' controlled substances sales.
- Who looks at the yearly data for sales of controlled substances and then, what is done, if anything? CCRM reviews include consideration of yearly controlled substances data. Factors suggesting the possibility of diversion are investigated, and any actual diversion discovered is reported to applicable authorities.

4. This case is being closed pursuant to Agent Manual Section 6232.32. All administrative aspects of this case have been completed. All original notes will be destroyed upon approval of this report by Group Supervisor James Graumlich.

ATTACHMENT

1. Responses to due diligence questions

INDEXING

[redacted]